UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

BAILEY SILVERMAN and LOUIS SILVERMAN,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	CIVIL ACTION H-10-1952
	§	
WATSON PHARMACEUTICALS, INC., *et al.*,	§	
	§	
Defendants.	§	

MEMORANDUM OPINION & ORDER

Pending before the court is defendants Watson Pharmaceuticals. Inc. and Watson Pharma, Inc.'s (collectively "the Watson defendants") motion for summary judgment. Dkt. 71. Upon consideration of the motion, the response, the reply, the summary judgment record, counsels' arguments at a hearing on this matter, and the applicable law, the motion is DENIED.

BACKGROUND

The court adopts the facts as related in its order on defendant Capsugel. Inc's motion for summary judgment on causation (Dkt. 116) and adds the following facts:

Although Bailey Silverman began taking Taztia XT in September 2008, she did not save any of her medication for testing until her last refill on December 29, 2008. Dkt. 71. Of that refill, she ingested 3 pills, sent 44 pills to the FDA for testing, and sent 12 pills to Kappa Laboratories. *Id.* The FDA's testing revealed only trace amounts of arsenic, within the tolerances submitted in Watson's ANDA.[1] Dkt. 72, Ex. F. The Kappa test results revealed arsenic levels in the hard gelatin capsules

[1] "An Abbreviated New Drug Application (ANDA) contains data which when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product." http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ (last visited Apr. 17, 2013).

over nine times greater than the amount Capsugel, Inc. reported on their Certificate of Analysis. Dkt. 92, Ex. I. Kappa Laboratories did not speciate, meaning differentiate, between organic and inorganic arsenic in its testing. *Id.*

At various points during Mrs. Silverman's illness, her doctors ran urine tests. Her initial test showed elevated arsenic. Dkt. 72, Ex. B. She had a follow-up test with Dr. Varon when she checked in to the emergency room, which was also elevated. *Id.* One she began the chelation therapy, the arsenic levels in Mrs. Silverman's urine tested normal. *Id.* When she finally returned home and resumed her previous habits—with the exception of taking the Taztia XT, her arsenic levels remained normal. Dkt. 92. All of the urine tests done on Mrs. Silverman either revealed organic arsenic or were not speciated between organic and inorganic. Dkt. 71.

LEGAL STANDARD

A motion for summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a); *see also Carrizales v. State Farm Lloyds*, 518 F.3d 343, 345 (5th Cir. 2008). A fact issue is "material" if its resolution could affect the outcome of the action. *Burrell v. Dr. Pepper/Seven Up Bottling Group, Inc.*, 482 F.3d 408, 411 (5th Cir. 2007). "[A]nd a fact is genuinely in dispute only if a reasonable jury could return a verdict for the [nonmovant]." *Fordoche, Inc. v. Texaco, Inc.*, 463 F.3d 388, 392 (5th Cir. 2006). Ultimately, "[w]here the record taken as a whole could not lead a rational trier of fact to find for the [nonmovant], there is no 'genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S. Ct. 1348 (1986).

When the movant bears the burden of proof on an issue, he must establish beyond peradventure *all* of the essential elements of the claims or defenses to warrant judgment in his favor. *Fontenot v. Upjohn Co.*, 780 F.2d 1190, 1194 (5th Cir. 1986) (emphasis in original). But when the

movant does not bear the burden of proof on a claim or affirmative defense, he bears the initial burden of production to show an absence of evidence to support the non-movant's claim. *TIG Ins. Co. v. Sedgwick James*, 276 F.3d 754, 759 (5th Cir. 2002). If the movant makes this showing, the ultimate burden to avoid summary judgment shifts to the non-movant who "must go beyond the pleadings and come forward with specific facts indicating a genuine issue for trial." *Davis-Lynch, Inc., v. Moreno*, 667 F.3d 539, 550 (5th 2012). Conclusory allegations and denials, speculation, improbable inferences, unsubstantiated assertions, and legalistic argumentation are no substitute for specific facts showing a genuine dispute for trial. *TIG Ins. Co.*, 276 F.3d at 759.

ANALYSIS

The Watson defendants move for summary judgment on five separate bases. As a threshold matter, the first two bases—that plaintiffs' failure to warn claims were barred by both Texas and Federal law—are now moot, since plaintiffs have formally abandoned their failure to warn claims. Dkt. 92. Therefore, the court need not address those arguments. The third argument—that the FDA has primary jurisdiction over this case—has already been addressed by this court. Dkt. 112. In the court's order on the Watson defendants' motions to exclude the testimony of Dr. Motyka, the court held that the purpose of the primary jurisdiction doctrine would not be served by placing the case on hold and declined to invoke it. Accordingly this argument is also moot. Therefore, the court will address only the last two arguments.

The Watson defendants argue that plaintiffs' claims that the Watson defendants breached a duty to monitor the safety of their drug products and report their findings to the FDA are barred because only the federal government may bring an action to enforce the provisions of the FDCA. They contend that plaintiffs may not bring claims that the Watson defendants violated specific FDA regulations covering good manufacturing practices, test methods, and standards because there is no

private right of action. Plaintiffs counter that the Watson defendants are confusing a freestanding federal enforcement action with a state law tort claim based on the premise that Mrs. Silverman's medication was defective, adulterated, and not safe for its intended and effective use. Plaintiffs further argue that the law clearly allows them to base this type of tort claim on violations of FDA regulations.

The court agrees. Plaintiffs are bringing products liability-type claims for a money remedy. They are not seeking for the court to order the Watson defendants to comply with FDA regulations—which they would likely not have standing to do anyway. So, the Watson defendants' quoted authority regarding the private right of action is inapposite. If, however, the Watson defendants are making a preemption argument, there are some instances where federal law in the field of drugs and medical devices will preempt state law remedies.[2]

In *Wyeth v. Levine*, the Supreme Court addressed the issue of whether the FDCA preempted state law failure to warn cases because of its specific labeling requirements. 555 U.S. 555, 129 S. Ct. 1187 (2009). The Court started from the premise that federal law does not preempt areas of state law absent the clear and manifest purpose of Congress. *Id.* at 565. Upon examining the plain language of the FDCA, which lacked any preemption language, and the history of the Act, the Court found that Congress had not intended the FDCA to preempt state law tort remedies in the area of pharmaceuticals.

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70–year history. But despite its 1976 enactment of an express pre-emption provision for medical devices . . . Congress has not enacted such a provision for prescription drugs. *See Riegel* [*v. Medtronic, Inc.*, 552 U.S. 312, 327, 128 S.Ct. 999, 1009

[2]For example, the Medical Device Amendments of 1976 to the FDCA specifically pre-empts certain cases where the device has undergone the FDA's premarket approval process ("PMA"). *See generally Funk v. Stryker Corp.*, 673 F.Supp.2d 522, 525 (S.D. Tex. 2009).

> (2008)] ("Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices"). Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness. As Justice O'Connor explained in her opinion for a unanimous Court: "The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–167, 109 S.Ct. 971, 103 L.Ed.2d 118 (1989) (internal quotation marks omitted); see also supra, at 1194 (discussing the presumption against pre-emption).

Id. at 574–75. The Watson defendants cite no direct authority stating that the specific tort claims brought by the Silvermans are preempted. And, in light of *Wyeth*, the onus is on the Watson defendants to demonstrate that these specific torts are preempted. They fall far short.

Last, the Watson defendants argue that there is no evidence that (1) their product was the substantial factor that caused Mrs. Silverman's illness; (2) Mrs. Silverman was exposed to harmful inorganic arsenic; and (3) the Watson defendants' product contained harmful inorganic arsenic. The Watson defendants' substantial factor argument is based on the Watson defendants' assertion that plaintiffs' expert have not ruled out *all* other sources of the arsenic. However, Texas law does not require that plaintiffs rule out all other sources. *See Shaun T. Mian Corp. v. Hewlett-Packard Co.*, 237 S.W.3d 851, 863 (Tex.App.–Dallas, pet. denied) ("[F]or circumstantial evidence to support inferences that a product was defective and the defect existed at the time it left the manufacturer, the evidence need not disprove all other possible causes for the injury."). That is not to say that plaintiffs need not rule out likely causes. *Id.* But here, plaintiffs have adduced evidence that Mrs. Silverman's treating doctor, Dr. Varon, ruled out various possibilities when he diagnosed her in the emergency room. Moreover, plaintiffs' other experts have addressed many of the Watson

defendants' proposed other sources. That is sufficient to demonstrate that a fact issue exists as to the source of the arsenic that Mrs. Silverman ingested.

The Watson defendants' arguments that Mrs. Silverman cannot demonstrate that she ingested harmful inorganic arsenic or that the Watson defendants' product contained harmful inorganic arsenic is premised on two conclusions regarding the different types of arsenic. The first conclusion is that all organic arsenic is safe to ingest. And the second conclusion is that the speciated results of a urinalysis showing organic arsenic in a person's body accurately reflect the form of the arsenic when it was ingested. Plaintiffs' forensic toxicology expert, Dr. Lykissa, testified that not all organic arsenic is innocuous. Dkt. 92, Ex. M. He further testified that the human body can process inorganic arsenic in such a way that it will appear organic when excreted in urine. Because this evidence calls into question the conclusions about arsenic on which the Watson defendants base their arguments, their ultimate conclusions regarding the plaintiffs' lack of proof must also fail.

CONCLUSION

Pending before the court is the Watson defendants's motion for summary judgment. Dkt. 71. Upon consideration of the motion, the response, the reply, the summary judgment record, counsels' arguments at a hearing on this matter, and the applicable law, the motion is DENIED.

It is so ORDERED.

Signed at Houston, Texas on April 17, 2013.

Gray H. Miller
United States District Judge